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ELX-5704 (US)

DATE: March 13, 2003 ATTORNEY DOCKET NUMBER: BXTD 9005PTO FACSIMILE NUMBER: 703/305-7939PLEASE DELIVER THIS FACSIMILE TO: Examiner Regina M. DeBerryTHIS FACSIMILE IS BEING SENT BY: Kathleen M. Petrillo, Esq.NUMBER OF PAGES: 7 INCLUDING COVER SHEETTIME SENT: 4:19 pm OPERATOR'S NAME Lori Macke

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Type of paper transmitted: Amendment BApplicant's Name: Lawrence H. ThompsonSerial No. (Control No.): 09/637,962 Examiner: Regina M. DeberryFiling Date: August 11, 2000 Art Unit: 1647Application Title: Therapeutic Methods for Treating Subjects With
a Recombinant Erythropoietin Having High
Activity and Reduced Side EffectsIF YOU DO NOT RECEIVE ALL PAGES CLEARLY, CALL BACK AS SOON AS
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BXTD 9005
ELX-5704 (US)
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of Lawrence H. Thompson

Art Unit 1647

Serial No. 09/637,962

Filed August 11, 2000

Confirmation No. 8001

For THERAPEUTIC METHODS FOR TREATING SUBJECTS WITH A RECOMBINANT
ERYTHROPOIETIN HAVING HIGH ACTIVITY AND REDUCED SIDE EFFECTS

Examiner Regina M. Deberry

15/D
H9J
3/24/03

March 13, 2003

AMENDMENT B

TO THE ASSISTANT COMMISSIONER FOR PATENTS,

SIR:

This amendment supplements Amendment A as filed January 9, 2003 in response to the Office action mailed September 9, 2002. Please enter the following amendments:

IN THE SPECIFICATION:

Please replace the paragraph beginning at page 15, line 4 with the following rewritten paragraph:

D' As mentioned in above, erythropoietins prepared from different DNA (genomic or cDNA) and/or in different cell lines have different glycosylation patterns and other attributes resulting in glycoproteins with differing biological activities. In the case of Epoetin Omega, broad peak fractions selected from a final isoelectric purification step, in vivo assay results using a polycythemic mouse assay typically show a range from about 40,000 to about 65,000 IU/mg. More narrowly selected peak fractions have an in vivo activity in the range of 90,000 IU to 120,000 IU per mg. For Epoetin Alfa, in vivo activity of pharmaceutical preparations typically are in the range of about 110,000 IU per mg. Pharmaceutical preparations are tested in a quality assurance / quality control process using the polycythemic mouse assay before being released for human use.